

REMARKS

The Final Office Action mailed on February 5, 2003, has been received and reviewed.

As the three-month shortened statutory period for response to the February 5, 2003, Office Action expired on May 5, 2003, this response is being filed along with a petition for a one-month extension of time and the appropriate fee.

Claims 25-34 are currently pending in the above-referenced application. Claims 25-29 stand rejected. Claims 30-34 have been withdrawn from consideration.

It is respectfully submitted that the proposed amendment of claim 25, which is made without prejudice or disclaimer, does not introduce new matter into the above-referenced application. Support for the proposed amendment is found, for example, at page 22, line 9, to page 23, line 20.

Reconsideration of the above-referenced application is respectfully requested.

I. 35 U.S.C. § 102(e)

A. King

Claim 25 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,633,724 to King et al. (hereinafter "King").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In the present case, the cited art fails to disclose the subject matter contained in the amended claims of the present invention.

King describes a biochemical assay system which includes, among other things, a waveguide with an array of reaction sites on a surface thereof. Each reaction site includes an eight-residue oligonucleotide, or "8-mer." King provides that the array of reaction sites is formed by the processes that are disclosed in U.S. Patent 5,143,854, issued to Pirrung et al. (hereinafter "Pirrung"), and incorporates by reference the disclosure of Pirrung in its entirety.

Pirrung describes that linker molecules may be provided on a substrate. Pirrung, col. 3, lines 8 & 9, and col. 8, lines 47 & 48. The linker molecules include protective groups which may be removed, for example, by exposure to a particular wavelength or range of wavelengths of electromagnetic radiation. Col. 3, lines 9-11, col. 8, lines 60-65. Once the protective group is removed, the linker molecules may react with and, thus, bind capture molecules or portions (*e.g.*, monomers) thereof. Col. 3, lines 14-17; col. 9, lines 14-19.

By way of contrast with King (and Pirrung, as incorporated by reference into King), independent claim 25, as proposed to be amended herein, recites a method which includes, among other things, “providing a waveguide . . . [with] at least one surface having a plurality of capture oligonucleotides immobilized *site-specifically to* substantially all regions of the at least one surface having a base coating thereon, the *base coating* being located *only on portions of the at least one surface . . .*” (emphasis supplied).

The originally-filed specification of the above-referenced application, at page 23, lines 6-11, clearly indicates that site-specific immobilization requires placement of a base coating onto desired regions of a substrate. Thereafter, the substrate is exposed to capture molecules. The capture molecules bind specifically to the sites on the substrate to which the base coating has been applied.

As the description of King, by way of the incorporated disclosure of Pirrung, is limited to applying a layer of activatable linker molecules to a surface of a substrate, the activating selected regions of such molecules, it is respectfully submitted that King lacks any express or inherent description of providing a waveguide that includes a base coating located only on portions of at least one surface thereof.

Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(e), King does not anticipate each and every element of amended independent claim 25. As King does not anticipate each and every element of independent claim 25, it is respectfully submitted that, under 35 U.S.C. § 102(e), independent claim 25 is allowable over King.

It is, therefore, respectfully requested that the 35 U.S.C. § 102(e) rejection of independent claim 25 be withdrawn.

II. 35 U.S.C. § 103(a)

It is respectfully submitted that, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the cited prior art reference must teach or suggest all of the claim limitations. Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the disclosure of the application at issue.

A. King in View of Squirrell

Claims 26, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over King in view of U.S. Patent 5,750,337 to Squirrell (hereinafter “Squirrel”).

The teachings of King are summarized above.

Squirrell teaches, among other things, a method for detecting nucleic acid sequences that employs a cylindrical waveguide. As depicted in FIG. 1 of Squirrell, light from an external source is coupled into the waveguide from an end thereof. The light is reflected within the cylindrical waveguide in such a way as to generate an evanescent field adjacent to the surfaces thereof. Capture molecules that have been immobilized to the surface of the cylindrical waveguide then bind both analyte and fluorescently labeled tracer molecules within one or more sample and/or test solutions. The evanescent field excites the fluorescent labels of the bound tracer molecules, causing them to fluoresce. Some of the fluorescent light is then coupled back into the cylindrical waveguide, where it is internally reflected. FIG. 1 of Squirrell shows that this internally coupled fluorescence may then be detected as it exits, or outcouples, an end of the cylindrical waveguide.

Like King, Squirrel lacks any teaching or suggestion of providing a waveguide which includes a base coating, to which capture oligonucleotides are site-specifically immobilized, on only portions of at least one surface thereof.

Claims 26, 28, and 29 are each allowable, among other reasons, as depending directly from claim 25, which is allowable.

B. King in View of Wybourne

Claim 27 is rejected under 35 U.S.C. § 103(a) as being unpatentable over King in view of U.S. Patent 5,465,151 to Wybourne et al. (hereinafter “Wybourne”).

The teachings of King are summarized above.

Wybourne teaches, among other things, an assay that employs a technique known as interferometry to detect the presence of analytes in a sample. A waveguide that is useful in interferometry, as illustrated in FIG. 1 of Wybourne, includes an incoming section, a first junction where the waveguide splits into two adjacent sections, a second junction where the two sections converge, and an outgoing section, from which light is detected. One of the two adjacent sections of the waveguide is used as a reference, while the other of the two adjacent sections is used to detect the amount of analyte, if any, present in a sample. The reference section does not have capture molecules immobilized relative thereto. The detection section does have capture molecules immobilized thereto. As light passes through the waveguide, the characteristics of the light that passes through the detection section thereof are altered, making the light that has passed through the detection section different than that which has traveled through the reference section. These differences are detected as light is coupled out of the waveguide through the outgoing section thereof and are indicative of the amount of analyte present in a sample solution.

As with King and Squirrel, Wybourne does not teach or suggest an assay which includes providing a waveguide with capture oligonucleotides site-specifically immobilized to a base coating, which only covers portions of at least one surface of the waveguide.

Claim 27 is allowable, among other reasons, as depending from claim 25, which is allowable.

Additionally, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine the teachings of King and Wybourne in the manner that has been asserted. Specifically, it is respectfully submitted that one of ordinary skill in the art would

not have been motivated to modify a fluorescence assay, such as that taught in King, with teachings that relate to an interferometry assay, such as that taught in Wybourne.

It is, therefore, respectfully submitted that the Office has not established a *prima facie* case as to the obviousness of claim 27 and that, under 35 U.S.C. § 103(a), claim 27 is allowable over the combination of Squirrell and Wybourne.

In view of the foregoing, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 26-29.

ENTRY OF AMENDMENT

It is respectfully submitted that the proposed amendment to claim 25 should be entered because it does not introduce new matter into the above-referenced application and would not require a new search. If a decision is made not to enter the proposed amendment to claim 25, entry thereof upon the filing of a Notice of Appeal in the above-referenced application is respectfully requested.

CONCLUSION

It is respectfully submitted that each of claims 25-29 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the referenced application has been passed for issuance. If any issues preventing the allowance of any of claims 25-29 remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power", with a long horizontal flourish extending to the right.

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